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10/511,591	08/10/2005	Denise Belsham	2223-188	2020
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McCarthy Tetrault LLP			GUCKER, STEPHEN	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,591

**Applicant(s)**

BELSHAM ET AL.

**Examiner**

Stephen Gucker

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 14, drawn to a cell line comprising a Glp-2 receptor marker, classified in Class 435, subclass 325+, for example.

Group II, claim(s) 1-2, 4 and 14, drawn to drawn to a cell line comprising a neurotensin marker, classified in Class 435, subclass 325+, for example.

Group III, claim(s) 1-2, 5 and 14, drawn to drawn to a cell line comprising a POMC marker, classified in Class 435, subclass 325+, for example.

Group IV, claim(s) 1-2, 6 and 14, drawn to drawn to a cell line comprising a NPY marker, classified in Class 435, subclass 325+, for example.

Group V, claim(s) 1-2, 7 and 14, drawn to drawn to a cell line comprising a proglucagon marker, classified in Class 435, subclass 325+, for example.

Group VI, claim(s) 1-2, 8 and 14, drawn to drawn to a cell line comprising a growth-hormone releasing hormone marker, classified in Class 435, subclass 325+, for example.

Group VII, claim(s) 1-2, 9 and 14, drawn to drawn to a cell line comprising a urocortin marker, classified in Class 435, subclass 325+, for example.

Group VIII, claim(s) 1-2, 10 and 14, drawn to drawn to a cell line comprising a melanocortin-concentrating hormone marker, classified in Class 435, subclass 325+, for example.

Group IX, claim(s) 1-2, 11 and 15, drawn to drawn to a cell line comprising a TenM 4 marker, classified in Class 435, subclass 325+, for example.

Group X, claim(s) 1-2, 12 and 14, drawn to drawn to a cell line comprising a growth hormone secretagogue receptor marker, classified in Class 435, subclass 325+, for example.

Group XI, claim(s) 1-2, 13 and 14, drawn to drawn to a cell line comprising a ghrelin marker, classified in Class 435, subclass 325+, for example.

Group XII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a TenM 1 marker, classified in Class 435, subclass 325+, for example.

Group XIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a TenM 2 marker, classified in Class 435, subclass 325+, for example.

Group XIV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a TenM 3 marker, classified in Class 435, subclass 325+, for example.

Group XV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a AVP marker, classified in Class 435, subclass 325+, for example.

Group XVI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a TRH marker, classified in Class 435, subclass 325+, for example.

Group XVII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a SOCS-3 marker, classified in Class 435, subclass 325+, for example.

Group XVIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a orexin marker, classified in Class 435, subclass 325+, for example.

Group XIX, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a dopamine transporter marker, classified in Class 435, subclass 325+, for example.

Group XX, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a gonadotropins-releasing hormone marker, classified in Class 435, subclass 325+, for example.

Group XXI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a CRF marker, classified in Class 435, subclass 325+, for example.

Group XXII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a gonadotropin releasing hormone receptor marker, classified in Class 435, subclass 325+, for example.

Group XXIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a tryptophan hydroxylase marker, classified in Class 435, subclass 325+, for example.

Group XXIV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a tyrosine hydroxylase marker, classified in Class 435, subclass 325+, for example.

Group XXV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a galanin marker, classified in Class 435, subclass 325+, for example.

Group XXVI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a proglucagon marker, classified in Class 435, subclass 325+, for example.

Group XXVII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a somatostatin marker, classified in Class 435, subclass 325+, for example.

Group XXVIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a agouti-related protein marker, classified in Class 435, subclass 325+, for example.

Group XXIX, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a CART marker, classified in Class 435, subclass 325+, for example.

Group XXX, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a leptin marker, classified in Class 435, subclass 325+, for example.

Group XXXI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a oxytocin marker, classified in Class 435, subclass 325+, for example.

Group XXXII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a CRF receptor 1 marker, classified in Class 435, subclass 325+, for example.

Group XXXIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a CRF receptor 2 marker, classified in Class 435, subclass 325+, for example.

Group XXXIV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a aromatase marker, classified in Class 435, subclass 325+, for example.

Group XXXV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising an androgen receptor marker, classified in Class 435, subclass 325+, for example.

Group XXXVI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising an estrogen receptor  $\alpha$  marker, classified in Class 435, subclass 325+, for example.

Group XXXVII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising an estrogen receptor  $\beta$  marker, classified in Class 435, subclass 325+, for example.

Group XXXVIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a leptin receptor marker, classified in Class 435, subclass 325+, for example.

Group XXXVIX, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a melancortin-concentrating hormone receptor 3 marker, classified in Class 435, subclass 325+, for example.

Group XL, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a melancortin-concentrating hormone receptor 4 marker, classified in Class 435, subclass 325+, for example.

Group XLI, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a NPY Y1 receptor marker, classified in Class 435, subclass 325+, for example.

Group XLII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a NPY Y2 receptor marker, classified in Class 435, subclass 325+, for example.

Group XLIII, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a calcitonin receptor like receptor marker, classified in Class 435, subclass 325+, for example.

Group XLIV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a glucagon-like peptide 1 receptor marker, classified in Class 435, subclass 325+, for example.

Group XLV, claim(s) 1-2 and 14, drawn to drawn to a cell line comprising a neurotensin receptor marker, classified in Class 435, subclass 325+, for example.

Groups XLVI-XC, claim 15, drawn to a method of obtaining a neuropeptide, Group XLVI corresponding to Group I (Glp-2 receptor), Group XLVII corresponding to Group II (neurotensin)... to Group XC corresponding to Group XLV (neurotensin receptor).

Groups XCI-CXXXV, claims 16-17, drawn to a method of identifying a modulator, Group XCI corresponding to Group I (Glp-2 receptor), Group XCII corresponding to Group II (neurotensin)... to Group CXXXV corresponding to Group XLV (neurotensin receptor).

Groups CXXXVI-CL, claims 19-21, Group CXXXVI corresponding to SEQ ID NO:1, Group CXXXVII corresponding to SEQ ID NO:2...Group CXLIV corresponding to SEQ ID NO:9, Group CXLV corresponding to TCAP-1, Group CXLVI corresponding to TCAP-3, Group CXLVII corresponding to N-7, Group CXLVIII corresponding to N-22, Group CXLIX corresponding to N-29, and Group CL corresponding to N-38

2. Claim 18 link(s) inventions CXXXVII-CL. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 18. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.



3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I is an immortalized cell line of murine hypothalamic neuronal cells comprising a gene encoding polyoma virus large T antigen and marker. However, Evrard et al. teaches brain cells from murine embryos transfected and immortalized by polyoma virus large T antigen (abstract, pages 1-2). Evrard et al. does not teach hypothalamic cell lines with a marker. Mellon et al. (IDS filed 11/28/05, 1995 reference) does teach immortalized hypothalamic cell lines comprising gonadotrophin-releasing hormone. It would have been obvious for one of ordinary skill in the art at the time of the invention to make a cell line using the polyoma virus large T antigen of Evrard et al. in combination with the murine hypothalamic cells of Mellon et al. in order to make a mixed culture of predominantly glial type cells so that "a system suitable for the biochemical analysis of the functions of glial cells, of glio-neuronal interactions and of the mechanisms involved in astroglial differentiation" could be used as a research tool (Evrard et al., page 3161). Because the technical feature of Group I does not involve an inventive step and is not an advancement over the prior art of record, it is not, by definition, a special technical feature and therefore Groups I-CL lack unit of invention.
4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number:  
10/511,591  
Art Unit: 1649

Page 12

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Gucker

April 10, 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649